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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/742,512	12/20/2000	Jean-Christophe Audonnet	454313-2541.2	8436

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EXAMINER

FORD, VANESSA L

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 02/21/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/742,512

Applicant(s)

AUDONNET ET AL.

Examiner

Vanessa L. Ford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2000.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-55 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-36 and 45 are drawn a combined enteric composition and kit, classified in class 424, subclass 203.1. Further species election is required.

Group II. Claims 37-43 are drawn to a method of immunizing in classified in class 435, subclass 7.1. Further species election is required.

Group III. Claims 44 and 55 ^{are} ~~is~~ drawn to a method of preparing a composition comprising antigens classified in class 435, subclass 69.3. Further species election is required.

Group IV. Claims 46-47 and 53-54 are drawn to hyperimmunized colostrum and a method of preparing, classified in class 424, subclass 184.1. Further species election is required.

2. The inventions are distinct, each from the other because of the following reasons:

Groups I and IV are drawn to different products. The claims of Group I are a combined enteric composition and kit drawn. The claims of Group IV are drawn to hyperimmunized colostrum and a method of preparing the hyperimmunized colostrum. The inventions are shown to be distinct because they are made by different methods and because they are physically and functionally distinct chemical entities.

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3. Groups I and II are related as product and process of use. These inventions can be shown to be distinct if either or both of the following can be shown. (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MEP 806.05(h)). In the instant case, the composition of Group I can be used in immunoassays.

4. Groups I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the method of preparing a composition comprising admixing antigens or epitopes or vectors and a carrier can be used to make a materially different composition comprising different antigens, epitopes and carriers.

5. Groups II and III are drawn to distinct methods which differ in the method objectives, method steps and in reagent used. The claims of Group are drawn to a method of immunizing. The claims of Group III are drawn to a method of preparing a composition.

6. Groups II and IV are related as product and process of use. These inventions can be shown to be distinct if either or both of the following can be shown. (1) the

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process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MEP 806.05(h)). In the instant case, the composition of Group IV can be used as a nutritional supplement.

7. Groups III and IV are unrelated as product and method of making. The product of Group IV is not need in the method of Group III. The inventions of each Group are independent and distinct as claimed.

SPECIES ELECTION

8. Group I contains claims 1-36 and 45 recite a plurality of disclosed patentably distinct inventions with distinct species. Applicant is advised to elect one species of animal selected from the group comprising bovine, canine, feline or equine species. Applicant is advised to elect a first antigen from the group comprising a *Cryptosporidium parvum* antigen, either a single antigen or mixture. If the Applicant elects a mixture, then the Applicant must specify the antigens that are included in the mixture. Applicant is advised to elect a second enteric antigen – a single or mixture from the group consisting of *E. coli*, rotavirus, coronavirus, *Clostridium* species and mixtures thereof. If Applicant elects a mixture at least two antigens must be elected. Applicant is also advised to elect a mode of presentation of the combined composition as recited in claim 1.

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9. Group II-IV contains claims 37-43, 44-55 and 46-47 and 53-54, respectively, recite methods that contain a plurality of disclosed patentably distinct inventions with distinct species. Applicant is advised to elect a mode of presentation of the combined composition as recited in claim 1.

10. The inventions are distinct, each from the other because of the following reasons: Because these inventions are distinct for the reasons given and have acquired a separate status in the art because of their recognized divergent subject matter as shown by their different classification, restriction for examination purposes as indicated is proper. Moreover, in the absence of restriction it would place an undue search and examination burden on the examiner.

11. Applicant is advised that the reply to this requirement to be complete must include an election of invention to be examined even though the requirement be traversed (37 CFR 1.143).

12. Applicant is reminded that upon that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

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13. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (703) 305-4735. The examiner can normally be reached on Monday – Friday from 7:30 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.



Vanessa L. Ford
Biotechnology Patent Examiner
February 19, 2002



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